



PTO/SB/08B (04-03)

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|----------------------|--------------------|
| Application Number   | 09/902,176         |
| Filing Date          | July 10, 2001      |
| First Named Inventor | Stefan Schreiber   |
| Art Unit             | 1634               |
| Examiner Name        | Sally A. Sakelaris |

Attorney Docket Number

25481-P001US

### NON PATENT LITERATURE DOCUMENTS

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|--------------------|-----------------------|---|----------------|
| Examiner Initials* | Cite No. <sup>1</sup> | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.                       | T <sup>2</sup> |
| <i>SS</i>          |                       | FABRIS, et al.; Tumor necrosis factor-alpha receptor II polymorphism in patients from southern Europe with mild-moderate and severe rheumatoid arthritis; Journal of Rheumatology; 2002 Sep; 29(9): 1847-50.  |                |
|                    |                       | OGILVIE, et al.; Treatment of psoriatic arthritis with antitumour necrosis factor-alpha antibody clears skin lesions of psoriasis resistant to treatment with methotrexate; Br. J. Dermatol.; 2001 Mar; 144(3):587-9.   |                |
|                    |                       | YEE AND POCHAPIN; Treatment of complicated sarcoidosis with infliximab anti-tumor necrosis factor-alpha therapy; Ann Intern Med. 2001 Jul 3; 135(1):27-31.  |                |
|                    |                       | ARINGER, et al; Safety and efficacy of tumor necrosis factor alpha blockade in systemic lupus erythematosus: an open-label study; Arthritis Rheum. 2004 Oct; 50(10):3161-9.   |                |
|                    |                       | BECKER, et al; TGF-Beta suppresses tumor progression in colon cancer by inhibition of IL-6 trans-signaling; Immunity, Vol 21, 491-501; October 2004, Cell Press.  |                |
|                    |                       | ROSE-JOHN AND NEURATH, et al.; IL-6 trans-signaling: The heat is on; Immunity; Vol 20, 1-20, January 2004, Cell Press.  |                |
|                    |                       | ATREYA, et al.; Blockade of interleukin 6 trans signaling suppresses T-cell resistance against apoptosis in chronic intestinal inflammation: Evidence in Crohn disease and experimental colitis in vivo; Nature Medicine, Volume 6, Number 5, 583-588; May 2000; Nature America, Inc. |                |
|                    |                       | RUTGEERTS, et al.; Treatment of active Crohn's disease with oncept (recombinant human soluble p55 tumour necrosis factor receptor): results of a randomized, open-label, pilot study; Aliment Pharmacol Ther. 2003 Jan; 17(2):185-92.   |                |
|                    |                       | DEN BROEDER, et al.; Long term anti-tumour necrosis factor alpha monotherapy in rheumatoid arthritis: effect on radiological course and prognostic value of markers of cartilage turnover and endothelial activation; Ann Rheum Dis 2002; 61:311-318.                                 |                |
| <i>SS</i>          |                       | CHOY, et al.; Efficacy of a novel PEGylated humanized anti-TNF fragment (CDP870) in patients with rheumatoid arthritis: a phase II double-blinded, randomized, dose-escalating trial; Rheumatology 2002; 41:1133-1137; British Society for Rheumatology.                              |                |

Examiner Signature

Date Considered

2/28/05

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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|--------------------|-----------------------|---|----------------|
| <i>SS</i>          |                       | SANDBORN, et al; An Engineered Human Antibody to TNF (CDP571) for Active Crohn's Disease: A Randomized Double-Blind Placebo-Controlled Trial; Gastroenterology 2001; 120:1330-1338; American Gastroenterological Association.                                   |                |
| <i>J</i>           |                       | ELLIOT, et al; Randomized double blind comparison of chimeric monoclonal antibody to tumor necrosis factor alpha (cA2) versus placebo in rheumatoid arthritis. Lancet 344:1105-1110, 1994.  |                |
| <i>BB</i>          |                       | ELLIOTT, et al.; Repeated therapy with monoclonal antibody to tumour necrosis factor alpha (cA2) in patients with rheumatoid arthritis; Lancet, October 22, 1994; 344(8930):1125-7  |                |
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| Examiner Signature | <i>John Schreiber</i> | Date Considered | 2/28/05 |
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